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10/590,118	06/11/2007	Prakash Singh Bisen	4544-062454	2820

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THE WEBB LAW FIRM, P.C.  
700 KOPPERS BUILDING  
436 SEVENTH AVENUE  
PITTSBURGH, PA 15219

EXAMINER
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SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,118	<b>Applicant(s)</b> BISEN ET AL.	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18August2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-21 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicants' Preliminary Amendment, received 18 August 2006, is acknowledged. Claims 1-10 have been canceled. New claims 11-21 have been added.
2. Claims 11-21 are pending and under consideration.

### Title

3. The following amendment of the title is suggested: Diagnostic Kit for Detecting Pulmonary and Extra Pulmonary Tuberculosis

### References

4. All of the references in the specification are improper as they are incomplete in the information required. Each reference should, at a minimum, include the author, journal, year, volume, number, and pages.

### Specification

5. The disclosure is objected to because of the following informalities:  
  
**Page 1**, line 2, add period immediately following "consuming"; line 8, "and specificity and specificity" should be "and specificity"; line 15, "product)" should be "product", what is the meaning of "are though sensitive".  
  
**Page 2**, line 8, "Negative" should be "negative"; line 10, "In accordance to" should be "In accordance with"; line 19 the name of the bacterium should be in italics, i.e., "*Mycobacterium tuberculosis*"; "strains" should be "strain"; line 21, "5000,-10,000" should be "5000-10,000"; "4-10 C" should be "4° - 10° C"; line 23, "at70-80C" should be "at 70° - 80° C".  
  
**Page 3**, line 3, what is "lypolized"? "Mycobacterial" should be "mycobacterial"; line 5, 16, 17, "whatman" should be "Whatman"; line 6, "The 1/5 volume" should be "A 1/5

volume"; line 10, define "C:M:W:3:48:47"; line 19, define "R.B. flask"; line 23, "Silica gel H activated" should be "silica gel H was activated"; line 27 what is the meaning of the superscripts in "(C:M:W)<sup>7,8</sup>".

**Page 4**, line 1, what is meant by "to run the column till other it reached the end"; line 8, "Methanol" should be "methanol"; line 10, "fraction" should be "fractions"; line 13, what is the method designated as "Liposome"; Lines 18 and 22, what is meant by "were taken"; line 21, "4°10°C" should be "4° - 10° C"; line 23, what is meant by "pre-prepared"; lines 25 and 29, "4° - 10 C" should be "4° - 10° C".

**Page 5**, line 7, "filterate was deproteinised" should be "filtrate was deproteinized"; line 10-11, "evaporated with the aid of rotary vacuum evaporated with the aid of rotary vacuum evaporator" should be "evaporated with the aid of rotary vacuum"; line 19, the name of the bacterium should be in italics, i.e., "*Mycobacterium tuberculosis*"; line 22, "was added" should be "were added"; line 23, what is meant by "shaken for 10 mm".

**Page 6**, line 7, what is meant by "so as to contain any contamination"; line 9, "Rabbits" should be "rabbits"; line 11, "Rabbit" should be "rabbit", "Negative" should be "negative"; line 15, what is meant by "as demonstrated on the test card"; line 16, what is meant by "in round conjugation"; lines 21-23, "and negative control (normal rabbit serum) and negative control (control rabbit serum) respectively", should be "and negative control (control rabbit serum) respectively"; line 25, how is the "dark blue" agglutination produced because there is no iteration of a dye previously in the procedures.

**Page 7**, line 1, what is meant by "No clumping on the card whereas, indicated a negative result."; line 7, what is an "outdoor patient"; line 10-11, what is meant by

"None of the patients was completely treated."; line 19, delete the comma immediately following "time".

**Page 8**, line 20-21, what is meant by "and rest two"; line 21, what is meant by "a need to chase these subjects".

**Page 9**, Table 1, the samples indicated as "\*\*\*" are called "indeterminate" in the table, but "indiscriminate" in the footnote, please explain or use only one term.

**Page 10**, Table 2, the samples indicated as "\*\*\*" are called "indeterminate" in the table, but "indiscriminate" in the footnote, please explain or use only one term.

Appropriate correction is required.

### **Claim Objections**

6. Claim 17 is objected to because of the following informalities: line 3, "Mycobacterium tuberculosis" should be in italics. Appropriate correction is required.

### **Claim Rejections - 35 USC § 112**

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 11-16, 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-14 are drawn to a kit for detecting pulmonary and extra pulmonary tuberculosis comprising a test card "TB Screen" coated with a hydrophobic material, an antigen suspension, a positive and a negative control. None of the claims provides an identity to the "antigen" being utilized. Therefore, it is unclear how the kit is for detecting pulmonary and extra pulmonary tuberculosis if none of the listed components are tuberculosis antigens.

Claims 15, 16, and 18-21 are drawn to a method of detecting tuberculosis using a kit comprising applying a positive control, a negative control, and a test sample. None of the claims provides an identity to the "antigen" being utilized. Therefore, it is unclear how the method can function for detecting tuberculosis if none of the listed components are tuberculosis antigens.

9. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is a method of detecting tuberculosis using a kit comprising a positive control prepared by growing *M. tuberculosis*, sonicating the bacteria, extracting with chloroform and methanol, filtering, and collecting "the lipid" and subjecting "the lipid" to the further step of purification.

It is unclear if "the lipid" denotes only one species of lipid, or is "the lipid" is actually a mixture of several *M. tuberculosis* lipids.

It is also unclear what step or steps are designated by "the further step of purification".

10. Claims 15-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method of detecting tuberculosis by observing a "dark blue" agglutination reaction. However, there is no "dark blue" dye added to the procedures. The only dye added is in claim 18, during the antigen purification procedures without any indication that the dye is actually present during the detection methods or is "dark blue" upon agglutination.

Thus, it is unclear how one obtains the required "dark blue" agglutination results.

### **Conclusion**

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.


If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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10/590,118  
Art Unit: 1645

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RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

January 4, 2008